28-35-135l. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned in this regulation: (a) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(b) "Leakage radiation" means radiation emanating from the device source assembly, except for the following:

(1) The useful beam; and

(2) radiation produced when the exposure switch or timer is not activated for diagnosis or therapy.

(c) "Leakage technique factors" means the technique factors associated with the tube housing assembly that are used in measuring leakage radiation. The leakage technique factors shall be defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential, with the quantity of charge per exposure being 10 millicoulombs or the minimum obtainable from the unit, whichever is larger;

(2) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated number of X-ray pulses in an hour for operation at the maximum rated peak tube potential; and

(3) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.

(d) "License" means a document issued in accordance with these regulations specifying the conditions of use of radioactive material.

(e) "Licensed or registered material" means radioactive material received, possessed, used, transferred, or disposed of under a general or specific license or registration issued by the department.

(f) "Licensee" means any person who is licensed in accordance with these regulations.

(g) "Licensing state" means any state that has been granted final designation by the conference of radiation control program directors, inc., for the regulatory control of NARM, as defined in K.A.R. 28-35-135n.

(h) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one plane in the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(i) "Line-voltage regulation" means the difference between the no-load and the load line potentials, expressed as a percent of the load line potential, using the following equation:

Percent line-voltage regulation = $100\ (V_n-V_l)/V_l$

where

V_n = No-load line potential and

V_l = Load line potential.

(j) "Local component" means any part of an analytical X-ray system. This term shall include components that are struck by X-rays, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. This term shall not include power supplies, transformers, amplifiers, readout devices, and control panels.

(k) "Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at a well site.

(l) "Logging tool" means a device used subsurface to perform well logging.

(m) "Lost or missing licensed or registered source of radiation" means a licensed or registered source of radiation whose location is unknown. This term shall include licensed or registered material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(n) "Lot tolerance percent defective" means the poorest quality, expressed as the percentage of defective units, in an individual inspection lot that may be accepted.

(o) "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate ~~in excess of 12~~ of less than or equal to two grays per hour at the point or surface where the dose is prescribed. (Authorized by K.S.A. 48-1607; implementing K.S.A. 48-1603 and 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL
MAY 28 2010
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DEPT. OF ADMINISTRATION
MAY 18 2010
APPROVED

28-35-135t. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned in this regulation: (a) "Target" means the part of a radiation head that by design intercepts a beam of accelerated particles, with the subsequent emission of other radiation.

(b) "Target-to-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source to the irradiated object or patient.

(c) "Technique factors" means the conditions of operation specified as follows:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses; and

(3) for all equipment not specified in paragraphs (c)(1) and (2), peak tube potential in kV and either the tube current in mA and the exposure time in seconds or the product of the tube current and the exposure time in mAs.

(d) "Teletherapy" means therapeutic irradiation in which the source of radiation is located at a distance from the body.

(e) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

(f) "Temporary job site" means a location where operations are performed and where sources of radiation may be stored, other than the location or locations of use authorized on the license or registration.

(g) "Tenth-value layer (TVL)" means the thickness of a specified material that attenuates X-radiation or gamma radiation to the extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(h) "Termination of irradiation" means the stopping of irradiation in a fashion not permitting the continuance of irradiation without the resetting of operating conditions at the control panel.

(i) "Test" means the process of verifying compliance with an applicable regulation.

(j) "Therapeutic dosage" means a dosage of unsealed ~~byproduct~~ by-product material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(k) "Therapeutic dose" means a radiation dose delivered from a source containing ~~byproduct~~ by-product material to a patient or human research subject for palliative or curative treatment.

(l) "Therapeutic-type tube housing" means the following:

(1) For X-ray equipment not capable of operating at 500 kVp or above, an X-ray tube housing constructed so that the leakage radiation, at a distance of one meter from the source, does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential; and

(2) for X-ray equipment capable of operating at 500 kVp or above, an X-ray tube housing constructed so that the leakage radiation, at a distance of one meter from the source, does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of the tube's operating conditions.

Areas of reduced protection shall be acceptable if the average reading over any area of 100 cm^2, at a distance of one meter from the source, does not exceed any of the values specified in this subsection.

(m) "These regulations" means article 35 in its entirety.

(n) "Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

(o) "Total effective dose equivalent" and "~~(~~TEDE~~)~~" ~~means~~ mean the sum of the ~~deep~~ effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(p) "Total organ dose equivalent" and "~~(~~TODE~~)~~" ~~means~~ mean the sum of the deep dose equivalent and the committed dose equivalent delivered to the organ receiving the highest dose.

(q) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons are documented.

(r) "Transport index" means the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the maximum radiation level in millirems per hour at one meter from the external surface of the package.

(s) "Tritium neutron-generator-target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

(t) "Tube" means an X-ray tube, unless otherwise specified.

(u) "Tube housing assembly" means the tube housing with a tube installed, including high-voltage transformers or filament transformers, or both, and other appropriate elements when contained within the tube housing.

(v) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as specified in a written directive.

(w) "Tube rating chart" means the set of curves that describes the rated limits of operation of the tube in terms of the technique factors.

(x) "Type A package" means packaging that, together with the radioactive contents limited to A_1 or A_2 as appropriate, is designed to retain the integrity of containment and shielding under normal conditions of transport as demonstrated by the tests specified in 49 CFR 173.465 or 49 CFR 173.466, as appropriate.

(y) "Type B package" and "type B transport container" mean packaging that meets the applicable requirements specified in 10 CFR 71.51. (Authorized by K.S.A. 48-

1607; implementing K.S.A. 48-1603 and 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

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DEPT. OF ADMINISTRATION

APR 22 2010

APPROVED

28-35-135w. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned in this regulation: (a) "Waste" means any low-level radioactive waste that is acceptable for disposal in a land disposal facility. Low-level radioactive waste shall mean radioactive waste that meets both of the following conditions:

(1) Is not classified as any of the following:

(A) High-level radioactive waste~~,~~ ;

(B) spent nuclear fuel~~,~~ ;

(C) "byproduct material," as defined in ~~the atomic energy act~~ 10 CFR 20.1003, dated December 1, 2009;

(D) uranium or thorium tailings~~,~~ ; and

(E) waste; and

(2) is classified as low-level radioactive waste consistent with existing law and in accordance with paragraph (a)(1) by the ~~U.S.~~ nuclear regulatory commission.

(b) "Waste-handling licensee" means any person licensed to receive and store radioactive wastes before disposal, any person licensed to dispose of radioactive waste, or any person licensed to both receive and dispose of radioactive waste.

(c) "Wedge filter" means an added filter effecting continuous, progressive attenuation of all or part of the useful beam.

(d) "Week" means seven consecutive days, starting on Sunday.

(e) "Weighting factor (w_T) for an organ or tissue (T)" means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 19 2010
APPROVED

of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T shall be as follows:

ORGAN OR TISSUE DOSE WEIGHTING FACTORS

Organ or Tissue (T)	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder organs	0.30[a]
Whole body	1.00[b]

[a] 0.30 results from 0.06 for each of the five remainder organs that receive the highest doses, excluding the skin and the lens of the eye.

[b] For the purpose of weighting the external whole body dose in determining the total effective dose equivalent, a single weighting factor, $w_T = 1.0$, is specified. The use of other weighting factors for external exposure may be approved by the secretary if the licensee or registrant demonstrates that the effective dose to be received is within the limits specified in these regulations.

(f) "Well bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

(g) "Well logging" means the lowering and raising of measuring devices or tools that could contain sources of radiation into well bores or cavities for the purpose of obtaining information about the well or adjacent formations.

(h) "Wet-source-change irradiator" means an irradiator whose sources are replaced underwater.

(i) "Wet-source-storage irradiator" means an irradiator whose sources are stored underwater.

(j) "Whole body," for purposes of external exposure, means the head and trunk, including the male gonads, and shall include the arms above the elbow and the legs above the knee.

(k) "Wireline" means a cable containing one or more electrical conductors that is used to raise and lower logging tools in the well bore.

(l) "Wireline service operation" means any evaluation or mechanical service that is performed in the well bore using devices on a wireline.

(m) "Worker" means an individual, contractor, or subcontractor engaged in work that is performed under a license or registration, or both, issued by the department and that is controlled by a licensee or registrant, or both. This term shall not include a specific licensee or registrant.

(n) "Working level (WL)" means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are the following:

(1) For radon-222, the following:

(A) Polonium-218;

(B) lead-214;

(C) bismuth-214; and

(D) polonium-214; and

(2) for radon-220, the following:

(A) Polonium-216;

(B) lead-212;

(C) bismuth-212; and

(D) polonium-212.

(o) "Working-level month (WLM)" means an exposure to one working level for 170 hours.

(p) "Written directive" means a written order for a specific patient that is dated and signed by an authorized user before the administration of a radiopharmaceutical or radiation and that contains any of the following sets of information:

(1) For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131, the radionuclide and dosage;

(2) for a therapeutic administration of a ~~radiopharmaceutical~~ radiopharmaceutical other than sodium iodide I-125 or I-131, the radiopharmaceutical, dosage, and route of administration;

(3) for gamma stereotactic radiosurgery, the target coordinates, collimator size, plug pattern, and total dose;

(4) for teletherapy, the total dose, dose per fraction, treatment site, and overall treatment period;

(5) for high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, and total dose; or

(6) for all other brachytherapy, the following information:

~~(i)~~ (A) Before implantation, the radionuclide, number of sources, and source strengths; and

~~(ii)~~ (B) after implantation but before completion of the procedure, the radionuclide, treatment site, and either the total source strength and exposure time or the total dose. (Authorized by K.S.A. 48-1607; implementing K.S.A. 48-1603 and 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

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DEPT. OF ADMINISTRATION

MAY 18 2010

APPROVED

28-35-175a. Persons licensed. (a) A licensed person shall not receive, use, possess, acquire, own, transfer, or dispose of radioactive material, except as authorized in a specific or general license issued pursuant to these regulations. Each manufacturer, producer, or processor of any equipment, device, commodity, or other product containing source or "byproduct material," as defined in 10 CFR 20.1003, dated December 1, 2009, for which subsequent receipt ~~possession~~, use, possession, acquisition, ownership, transfer, and disposal by any other person is exempted from these regulations shall obtain authority to transfer possession or control to the other person from the ~~U.S.~~ nuclear regulatory commission.

(b) In addition to the requirements of this part, each licensee shall be subject to the requirements of part 1, part 4, and part 10 of these regulations. In addition to being subject to part 1, part 4, and part 10, specific licensees shall be subject to all of the following requirements:

(1) Licensees using radioactive material in the healing arts shall be subject to the requirements of part 6.

(2) Licensees using radioactive material in industrial radiography shall be subject to the requirements of part 7.

(3) Licensees using radioactive material in wireline and subsurface tracer studies shall be subject to the requirements of part 11 of these regulations. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

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DEPT. OF ADMINISTRATION

MAY 18 2010

APPROVED

28-35-178b. General license; certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. (a) (1) Subject to the provisions of subsections (b) and (c), each commercial and industrial firm, research, educational, and medical institution, individual in the conduct of the individual's business, and federal, state, or local government agency shall be deemed to have been issued a general license to acquire, receive, possess, use, or transfer radioactive material that is contained in any device designed, manufactured, and used for one or more of the following purposes:

(A) Detecting, measuring, gauging, or controlling thickness, density, level interface location, radiation leakage, or qualitative or quantitative chemical composition; or

(B) producing light or an ionized atmosphere.

(2) The general license specified in paragraph (1) of this subsection shall apply only to radioactive material contained in any device that has been manufactured and labeled by a manufacturer in accordance with the specifications of a specific license issued to that manufacturer by the secretary, the ~~U.S.~~ nuclear regulatory commission, or an agreement state.

(3) The general license specified in paragraph (1) of this subsection shall not apply to radioactive material in any device containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element, based on the activity indicated on the label.

(4) Each device shall have been received from one of the specific licensees described in paragraph (a)(2) or through a transfer made under paragraph (b)(9).

(b) Each person who acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license specified in subsection (a) shall comply with all of the following requirements:

(1) Each person subject to this subsection shall ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained and shall comply with all instructions and precautions provided by these labels.

(2) Each person subject to this subsection shall ensure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at any other intervals specified in any manufacturer's label affixed to the device, except as follows:

(A) The person shall not be required to test devices containing only krypton for leakage of radioactive material.

(B) The person shall not be required to test, for any purpose, any device containing only tritium, not more than 100 microcuries of other beta-emitting or gamma-emitting material, or 10 microcuries of alpha-emitting material or any device held in storage in the original shipping container before initial installation.

(3) Each person subject to this subsection shall ensure that the tests required by paragraph (b)(2) and other operations involving testing, installation, servicing, and

removal from installation of the radioactive material, its shielding, or containment, are performed in compliance with one of the following:

(A) In accordance with instructions provided on labels affixed to the device; or

(B) by a person holding a specific license issued under this part or equivalent regulations of NRC or an agreement state to perform the tests and other operations.

(4)(A) Each person subject to this subsection shall maintain records showing compliance with the requirements of paragraphs (b)(2) and (b)(3). The records shall show the results of each test. The records also shall show the dates of the testing, installation, servicing, or removal from installation of the radioactive material, its shielding, or containment and the name of each person performing one or more of these tests and other operations.

(B) Each person shall maintain records of tests for leakage of radioactive material required by paragraph (b)(2) for three years after the next required leak test is performed or until the sealed source is transferred or disposed of. Each person shall maintain records of tests of the on-off mechanism and indicator, as required by paragraph (b)(2), for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Each person shall maintain the records required by paragraph (b)(3) for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, each person subject to this subsection shall take the following actions:

(A) Immediately suspend operation of the device until either of the following conditions is met:

(i) The device has been repaired by the manufacturer or other person holding a specific license issued under this part or equivalent regulations of NRC or an agreement state to repair the device; or

(ii) the device is transferred to a person authorized by a specific license to receive the radioactive material contained in the device;

(B) within 30 days, furnish to the secretary a report containing a brief description of the event and the remedial action taken; and

(C) within 30 days, if contamination of the premises or the environs is likely, furnish to the secretary a plan for ensuring that the premises and environs are acceptable for unrestricted use. The criteria for unrestricted use specified in K.A.R. 28-35-205 may be applicable, as determined by the secretary.

(6) A person subject to this subsection shall not abandon the device.

(7) A person shall not export any device containing radioactive ~~byproduct~~ material except in accordance with 10 CFR part 110.

(8) (A) Each person shall transfer or dispose of any device containing radioactive ~~byproduct~~ material only by export as provided in paragraph (b)(7), by transfer to another general licensee as authorized in paragraph (b)(9), or to a person authorized to receive the device by a specific license issued under this part or equivalent regulations of NRC or an agreement state.

(B) Each person shall furnish a report to the department within 30 days after the export of the device or the transfer of the device to a specific licensee. The report shall contain the following information:

(i) The identification of the device by manufacturer's name, model number, and serial number;

(ii) the name, address, and license number of the person receiving the device; and

(iii) the date of the transfer.

(C) Each person shall obtain written department approval before transferring the device to any other specific licensee not specifically identified in paragraph (b)(8)(A). The holder of a specific license may transfer a device for possession and use under its own specific license without approval, if the holder performs the following:

(i) Either verifies that the specific license authorizes the possession and use or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) ensures that the device is labeled in compliance with these regulations. The label shall retain the name of the manufacturer, the model number, and the serial number;

(iii) obtains the manufacturer's or initial transferor's information concerning maintenance, including leak testing procedures that are applicable under the specific license; and

(iv) reports the transfer as required by paragraph (b)(8)(B).

(9) Any person subject to this subsection may transfer the device to another general licensee only if either of the following conditions is met:

(A) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this regulation and any safety documents identified in any label affixed to the device and, within 30 days of the transfer, provide a written report to the secretary containing identification of the device by manufacturer's name, model number, and serial number; the name and address of the transferee; and the name, telephone number, and position of an individual who can be contacted by the secretary concerning the device.

(B) The device is held in storage in the original shipping container at its intended location of use before initial use by a general licensee.

(10) Each person subject to this subsection shall comply with the provisions of K.A.R. 28-35-228a and K.A.R. 28-35-229a relating to reports of radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of parts 4 and 10 of these regulations.

(11) Each person shall respond to all written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request or on or before any other deadline specified in the request. If the person cannot provide the requested information within the allotted time, the person, within that same time period, shall request a longer period to supply the information by submitting a letter to the department and shall provide written justification as to why the person cannot comply.

(12) Each general licensee shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure day-to-day compliance with the appropriate regulations and requirements. This appointment shall not relieve the general licensee of any of the licensee's responsibility in this regard.

(13)(A) Each person shall register, in accordance with paragraph (b)(13)(B), each device generally licensed as required by this regulation. Each address for a location of use, as described in paragraph (b)(13)(B)(iv), shall represent a separate general licensee and shall require a separate registration and fee.

(B) In registering each device, the general licensee shall furnish the following information and any other information specifically requested by the department:

(i) The name and mailing address of the general licensee;

(ii) information about each device as indicated on the label, including the

manufacturer's name, the model number, the serial number, and the radioisotope and activity;

(iii) the name, title, and telephone number of the responsible person appointed as a representative of the general licensee under paragraph (b)(12);

(iv) the address or location at which each device is used or stored, or both. For each portable device, the general licensee shall provide the address of the primary place of storage;

(v) certification by the responsible representative of the general licensee that the information concerning each device has been verified through a physical inventory and a check of the label information; and

(vi) certification by the responsible representative of the general licensee that the person is aware of the requirements of the general license.

(14) Each person shall report any change in the mailing address for the location of use, including any change in the name of the general licensee, to the department within 30 days of the effective date of the change. For a portable device, a report of address change shall be required only for a change in the primary place of storage of the device.

(15) No person may store a device that is not in use for longer than two years. If any device with shutters is not being used, the shutters shall be locked in the closed position. The testing required by paragraph (b)(2) shall not be required to be performed during the period of storage only. If the device is put back into service or transferred to another person and was not tested at the required test interval, the device shall be tested

for leakage before use or transfer, and all shutters shall be tested before use. Each device kept in storage for future use shall be excluded from the two-year time limit if the general licensee performs quarterly physical inventories of the device while the device is in storage.

(c) Nothing in this regulation shall be deemed to authorize the manufacture or import of any device containing radioactive material.

(d) The general license specified in subsection (a) shall be subject to the provisions of K.A.R. 28-35-184a and K.A.R. 28-35-184b. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Nov. 1, 1996; amended March 24, 2006; amended July 27, 2007; amended P-_____.)

28-35-178e. Americium-241 or radium-226 in the form of calibration or reference sources. (a) A general license to acquire, possess, use and transfer, in accordance with the provisions of ~~subsection~~ subsections (b) and (c) ~~of this section~~, americium-241 or radium-226 in the form of calibration or reference sources is hereby issued to any person who holds a specific license issued by the ~~U.S.~~ nuclear regulatory commission ~~which~~ that authorizes the agency to acquire, possess, use, and transfer by-product material, source material, or special nuclear material.

(b) The general license issued in subsection (a) ~~of this section applies~~ shall apply only to calibration or reference sources ~~which~~ that have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the secretary, the ~~U.S.~~ nuclear regulatory commission, or an agreement state.

(c) The general license issued in subsection (a) ~~of this section is~~ shall be subject to the provisions of K.A.R. 28-35-184a, and to all of the provisions of parts 4 and 10 of these regulations. In addition, persons who acquire, possess, use, and transfer one or more calibration or reference sources pursuant to this general license shall meet the following requirements:

(1) ~~Shall~~ Not possess, at any one time, at any one location of storage or use, more than 5 microcuries of either americium-241 or radium-226 in such sources;

(2) ~~shall~~ not receive, possess, use, or transfer such a source unless the source, or the storage container, bears a label ~~which~~ that includes the following statement or a substantially similar statement ~~which~~ that contains the information called for in the following statement:

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
APR 23 2010
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"The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)";

(3) ~~shall~~ not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license issued by the secretary, the ~~U.S.~~ nuclear regulatory commission, or ~~by~~ an agreement state to receive the source;

(4) ~~shall~~ store such source, except when the source is being used, in a closed container designed and constructed to contain either americium-241 ~~which~~ or radium-226 that might otherwise escape during storage; and

(5) ~~shall~~ not use the source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) The general license issued in this regulation shall not authorize the manufacture, or the importation or exportation, of calibration or reference sources containing either americium-241 or radium-226. (Authorized by and implementing

K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 23 2010

APPROVED

28-35-178j. General license for use of ~~byproduct~~ radioactive material for certain in vivo clinical or laboratory testing. (a) Except as provided in subsections (b) and (c), each person shall be exempt from the license requirements in part 3 and part 6 of these regulations if the person receives, possesses, uses, transfers, owns, or acquires any capsules containing 37 kBq (1 μCi) of carbon-14 urea, allowing for nominal variation that may occur during the manufacturing process for in vivo diagnostic use for humans.

(b) Before using the capsules specified in subsection (a) for research involving human subjects, each person shall apply and shall be considered for approval for a specific license. Each person shall be required to have a specific license before engaging in the research specified in this subsection.

(c) Before manufacturing, preparing, processing, producing, packaging repackaging, or transferring the capsules specified in subsection (a) for commercial distribution, each person shall apply and shall be considered for approval for a specific license. Each person shall be required to have a specific license before performing any of the actions specified in this subsection.

(d) Nothing in this regulation shall exempt any person from applicable FDA requirements, other federal requirements, and state requirements governing receipt, administration, and use of drugs. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 23 2010

APPROVED

28-35-180b. Financial assurance for decommissioning. (a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities specified in K.A.R. 28-35-201 shall submit a decommissioning funding plan as described in ~~subsection~~ K.A.R. 28-35-180b(e) ~~of this regulation~~. Each applicant shall also submit the decommissioning funding plan if a combination of isotopes is involved and if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value specified in K.A.R. 28-35-201.

(b) Each applicant for a specific license authorizing the possession and use of radioactive material with a half-life greater than 120 days and in quantities specified in table I ~~of this regulation~~ shall submit either of the following:

(1) A decommissioning funding plan as described in subsection (e) ~~of this regulation~~; or

(2) a certification that financial assurance for decommissioning has been provided in the amount prescribed by table I, using one of the methods described in subsection (f) ~~of this regulation~~. The certification may state that the appropriate assurance is to be obtained after the application has been approved and the license has been issued, but before the receipt of licensed material. If the applicant defers execution of the financial instrument required under subsection (f) until after the license has been issued, a signed original of the financial instrument shall be submitted to the department before the applicant receives the licensed material. If the applicant does not defer execution of the financial instrument required under subsection (f) ~~of this regulation~~, the applicant shall

submit to the department, as part of the certification, a signed original of the financial instrument.

(c) Each holder of a specific license that is a type specified in subsection (a) or (b) shall provide financial assurance for decommissioning in accordance with the following requirements:

(1) Each holder of a specific license that is a type specified in subsection (a) shall submit a decommissioning funding plan as specified in subsection (e) or a certification of financial assurance for decommissioning in an amount equal to at least ~~$750,000.00~~ $1,125,000.00. Each licensee shall submit the plan or certification to the department in accordance with the criteria specified in this regulation. If the licensee submits a certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(2) Each holder of a specific license that is a type specified in subsection (b) shall submit a decommissioning funding plan as specified in subsection (e) or a certification of financial assurance for decommissioning. Each licensee shall submit the plan or certification to the department, in accordance with the requirements specified in this regulation.

(d) The amounts of financial assurance required for decommissioning, by quantity of material, shall be those specified in table I.

Table I

Financial assurance for decommissioning by quantity of material

If the possession limit is greater than 10^4 but less than or equal to 10^5 times the applicable quantities specified in K.A.R. 28-35-201, in unsealed form	$1,125,000.00
For a combination of isotopes, in unsealed form, if R, as defined in subsection (a), divided by 10^4 is greater than one, but R divided by 10^5 is equal to or less than one	$1,125,000.00
If the possession limit is greater than 10^3 but less than or equal to 10^4 times the applicable quantities specified in K.A.R. 28-35-201, in unsealed form	$225,000.00
For a combination of isotopes, in unsealed form, if R, as defined in subsection (a), divided by 10^3 is greater than one, but R divided by 10^4 is less than or equal to one	$225,000.00
If the possession limit is greater than 10^{10} times the applicable quantities specified in K.A.R. 28-35-201, in sealed sources or foils	$113,000.00
For a combination of isotopes, in sealed sources or foils, if R, as defined in subsection (a), divided by 10^{10} is greater than one	$113,000.00

(e) Each decommissioning funding plan shall contain the following:

(1) A cost estimate for decommissioning;

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
JAN 11 2010
APPROVED

(2) a description of the method of ensuring funds for decommissioning, selected from the methods specified in subsection (f);

(3) a description of the means for periodically adjusting cost estimates and associated funding levels over the life of the facility;

(4) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(5) a signed original of the financial instrument obtained to satisfy the requirements specified in subsection (f).

(f) Each licensee shall provide financial assurance for decommissioning by one or more of the following methods.

(1) Prepayment. "Prepayment" shall mean cash or liquid assets that meet the following criteria:

(A) Before the start of operation, are deposited into an account that is segregated from the licensee's assets and outside of the licensee's administrative control; and

(B) consist of an amount that is sufficient to pay decommissioning costs.

The prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety instrument, insurance policy, or other guarantee method. The licensee may use a surety instrument, insurance policy, or other similar means to guarantee that decommissioning costs will be paid. A surety instrument may be in the form of a surety bond, letter of credit, or line of credit. A parent company's guarantee of funds for

decommissioning costs based on a financial test may be used if the guarantee and test meet the requirements of K.A.R. 28-35-203. A parent company's guarantee shall not be used in combination with other financial methods to meet the requirements in this regulation. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test meet the requirements of K.A.R. 28-35-203. A guarantee by the applicant or licensee shall not be used in combination with any other financial methods to meet the requirements in this regulation or in any situation in which a parent company of the applicant or licensee holds majority control of the voting stock of the company. Each surety instrument or insurance policy used to provide financial assurance for decommissioning shall contain the following ~~conditions~~ requirements:

(A) The surety instrument or insurance policy shall be open-ended or, if written for a specified term, shall be renewed automatically, unless 90 days or more before the renewal date, the insurer notifies the department, the beneficiary, and the licensee of the insurer's intention not to renew. The surety instrument or insurance policy shall also provide that the full face amount will be paid to the beneficiary automatically before the expiration without proof of forfeiture if the licensee fails to provide a replacement that meets the requirements of this regulation within 30 days after receipt of notification of cancellation.

(B) The surety instrument or insurance policy shall be payable to an approved trust established for decommissioning costs. The trustee may include an appropriate state

or federal agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(C) The surety instrument or insurance policy shall remain in effect until the license is terminated by the department.

(3) External sinking fund. A licensee may provide financial assurance for decommissioning through an external sinking fund in which deposits are made at least annually, coupled with a surety instrument or insurance policy. The value of the surety instrument or insurance policy may decrease by the amount accumulated in the sinking fund. "External sinking fund" shall mean a fund that meets both of the following conditions:

(A) Is established and maintained by setting aside funds periodically in an account segregated from the licensee's assets and outside the licensee's administrative control; and

(B) contains a total amount of funds sufficient to pay the decommissioning costs when termination of the operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall meet the requirements specified in this subsection.

(4) Statement of intent. Any federal, state, or local government licensee may submit a statement of intent containing a cost estimate for decommissioning or an amount

based on table I of this regulation and indicating that funds for decommissioning will be obtained when necessary.

(g) Each person licensed under subsections (a) through (g) shall keep records of all information that is relevant to the safe and effective decommissioning of the facility. The records shall be kept in an identified location until the license is terminated by the department. If records of relevant information are kept for other purposes, the licensee may refer to these records and the location of these records within the records kept pursuant to this subsection.

(h) Each licensee shall maintain decommissioning records, which shall consist of the following information:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to records of instances in which contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants could have spread to inaccessible areas. These records shall include any known information identifying the nuclides, quantities, forms, and concentrations involved in the spill or occurrence;

(2) drawings of the following, both as originally built and, if applicable, as modified:

(A) The structures and equipment in restricted areas where radioactive materials are used or stored, or both; and

(B) the locations of possible inaccessible contamination. If the licensee refers to required drawings other than those kept pursuant to this regulation, the licensee shall not be required to index each relevant document individually. If drawings are not available, the licensee shall substitute available information concerning these areas and locations;

(3) a list of the following information, which shall be contained in a single document and updated every two years:

(A) All areas designated and formerly designated as restricted areas;

(B) all areas outside of restricted areas that require the documentation specified in this subsection;

(C) all areas outside of restricted areas where current and previous wastes have been buried and documented as specified in K.A.R. 28-35-227j; and

(D) all areas outside of restricted areas that contain material so that, if the license expired, the licensee would be required either to decontaminate the area to unrestricted release levels or to apply for approval for disposal as specified in K.A.R. 28-35-225a.

Those areas containing sealed sources only shall not be included in the list if the sources have not leaked, no contamination remains in the area after any leak, or the area contains only radioactive materials having half-lives of less than 65 days; and

(4) the following records:

(A) Records of the cost estimate performed for the decommissioning funding plan or records of the amount certified for decommissioning; and

(B) if either a funding plan or certification is used, records of the funding method used for assuring funds.

(i) Each applicant for a specific license shall make arrangements for a long-term care fund pursuant to K.S.A. 48-1623, and amendments thereto. Each applicant for any of the following types of specific licenses shall establish the long-term care fund before the issuance of the license or before the termination of the license if the applicant chooses, at the time of licensure, to provide a surety instrument in lieu of a long-term care fund:

(1) Waste-handling licenses;

(2) source material milling licenses; and

(3) licenses for any facilities formerly licensed by the U.S. atomic energy commission or the ~~U.S.~~ nuclear regulatory commission, if required.

(j)(1) Each applicant shall agree to notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11, bankruptcy, of the United States code by or against any of the following:

(A) The licensee;

(B) any person controlling the licensee or listing the license or licensee as property of the estate; or

(C) any affiliate of the licensee.

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 23 2010

APPROVED

(2) The bankruptcy notification shall indicate the following:

(A) The name of the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date on which the petition was filed. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-_____.)

28-35-181a. Specific licenses for ~~materials,~~ human use of radioactive material in medical institutions. An application for a specific license for human use of radioactive material in institutions shall not be approved unless all of the following conditions are met:

(a) The applicant has appointed a radiation safety committee ~~of at least three members to oversee the licensed radioactive material throughout the institution and to review the institution's radiation safety program. Membership of the committee shall include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institution's management, and a radiation safety officer;~~ as specified in 10 CFR 35.24(f), which is adopted by reference in K.A.R. 28-35-264.

(b) The applicant possesses adequate facilities for the clinical care of patients~~;~~ .

(c) The physician or physicians designated on the application as the user or users have substantial experience in handling and administering radioactive materials~~;~~ and ~~where~~, if applicable, clinical management of radioactive patients~~; and~~ .

(d) If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant or applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses. (Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL DEPT. OF ADMINISTRATION

MAY 28 2010 APR 23 2010

APPROVED BY APPROVED

28-35-181e. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; revoked P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 23 2010

APPROVED

28-35-181j. ~~Special~~ Specific licenses to manufacture and distribute calibration sources containing americium-241 or ~~plutonium~~ radium-226. ~~An application for a specific license to manufacture calibration sources containing americium-241 or plutonium and to distribute those sources to persons generally licensed under K.A.R. 28-35-178e shall not be approved unless the applicant meets the requirements of sections 32.57, 32.58, 32.59 and 32.102 of 10 CFR Part 32, as in effect on May 31, 1984, and the requirements of section 70.39 of 10 CFR Part 70, as in effect on May 31, 1984.~~ (a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under K.A.R. 28-35-178e shall not be approved unless the following requirements are met:

(1) The applicant shall satisfy the general requirements of part 3 of these regulations.

(2) The applicant shall submit sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including the following:

(A) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(B) details of construction and design;

(C) details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
APR 23 2010
APPROVED

(D) procedures for and results of prototype testing of sources that are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(E) details of quality control procedures to be followed in manufacture of the source;

(F) description of labeling to be affixed to the source or the storage container for the source; and

(G) any additional information, including experimental studies and tests, required by the department to facilitate a determination of the safety of the source.

(3) Each source shall contain no more than 5 μCi of americium-241 or radium-226.

(4) The method of incorporation and binding of more than 0.005 μCi of the americium-241 or radium-226 in the source shall prevent the release or removal of americium-241 or radium-226 from the source under normal conditions of use and handling of the source.

(5) The applicant shall conduct prototype tests, in the order listed, on each of five prototypes of the source containing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

(A) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(B) Dry wipe test. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(C) Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after the paper has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(D) Water soak test. The source shall be immersed in water at room temperature for 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after the source has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(E) Dry wipe test. On completion of the water soak test, the dry wipe test described in paragraph (a)(5)(B) shall be repeated.

(F) Observations. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by paragraph (a)(5) shall be cause for rejection of the source design. Results of prototype tests submitted to the nuclear regulatory commission shall be given

in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(6) Each source or storage container for the source shall have a label affixed that contains sufficient information about safe use and storage of the source and includes the following or an equivalent statement:

"The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)."

(b) Each person licensed under this regulation shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. This test shall be performed by wiping the entire radioactive

surface of the source with a filter paper with the application of moderate finger pressure.

The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee in accordance with K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. (Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 18 2010
APPROVED

28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use. An application for a specific license to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material and used by persons as specified in part 6 of these regulations shall not be approved unless the applicant meets the requirements of this regulation and all other applicable requirements of these regulations.

(a) ~~The~~ Each applicant shall meet the requirements specified in K.A.R. 28-35-180a.

(b) ~~The~~ Each applicant shall submit evidence of either of the following:

(1) The radiopharmaceutical containing radioactive material is subject to the federal food, drug and cosmetic act or the public health service act and will be manufactured, labeled, and packaged in accordance with a new drug application (NDA) approved by the food and drug administration (FDA), a biologic product license issued by the FDA, or a "notice of claimed investigational exemption for a new drug" (IND) accepted by the FDA.

(2) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal food, drug, and cosmetic act or the public health service act.

(c) Each applicant shall submit evidence of at least one of the following:

(1) The applicant is registered or licensed with the U.S. food and drug administration as a drug manufacturer.

(2) The applicant is registered or licensed with a state agency as a drug manufacturer.

(3) The applicant is licensed as a pharmacy by the state board of pharmacy.

(4) The applicant is operating as a nuclear pharmacy within a federal medical institution.

(5) The applicant is operating a positron emission tomography (PET) drug production facility.

(d) ~~The~~ Each applicant shall submit the following information on the radionuclide:

(1) The chemical and physical form of the material;

(2) the packaging in which the radionuclide is shipped, including the maximum activity per package; and

(3) evidence that the shielding provided by the packaging of the radioactive material is appropriate for the safe handling and storage of radiopharmaceuticals by group licensees.

(e) (1) ~~The~~ Each applicant shall submit a description of the following:

(A) A label that shall be affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the following:

(i) The radiation symbol and the words "CAUTION -- RADIOACTIVE MATERIAL" or "DANGER -- RADIOACTIVE MATERIAL";

(ii) the name of the radioactive drug and the abbreviation; and

(iii) the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(B) a label that shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION -- RADIOACTIVE MATERIAL" or "DANGER -- RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) The labels, leaflets, or brochures required by this regulation shall be made in addition to the labeling required by the FDA. The labels, leaflets, or brochures may be separate from the FDA labeling, or with the approval of the FDA, the labeling may be combined with the labeling required by the FDA.

(f) All of the following shall apply to each licensee described in paragraph (c)(3) or (c)(4), or both:

(1) The licensee may prepare radioactive drugs for medical use, if each radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (2) and (4) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist.

(2) The licensee may allow a pharmacist to work as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The pharmacist qualifies as an authorized nuclear pharmacist.

(B) The pharmacist meets the requirements specified in 10 CFR 35.55 (b) and 35.59, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(C) The pharmacist is designated as an authorized nuclear pharmacist in accordance with paragraph (4) of this subsection.

(3) The actions authorized in paragraphs (1) and (2) of this subsection shall be permitted in spite of more restrictive language in license conditions.

(4) The licensee may designate a pharmacist as an authorized nuclear pharmacist if the individual ~~was~~ is a nuclear pharmacist preparing radioactive drugs and identified ~~on or before December 2, 1994~~ as an "authorized user" on a nuclear pharmacy license issued under this part.

(5) Each licensee shall provide the following to the department no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(A) and (2)(C) of this subsection, the individual to work as an authorized nuclear pharmacist:

(A) A copy of each individual's certification by the board of pharmaceutical specialties, the department or agreement state license, or the permit issued by a licensee of broad scope; and

(B) a copy of the state pharmacy license or registration.

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
APR 23 2010
APPROVED

(g) Each licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. Each licensee shall have procedures for using the instrumentation. Each licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before transfer for commercial distribution. Each licensee shall meet the following requirements:

(1) Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments if necessary; and

(2) check each instrument for constancy and proper operation at the beginning of each day of use.

(h) Nothing in these regulations shall exempt the licensee from the requirement to comply with applicable FDA requirements and other federal and state requirements governing radioactive drugs. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended July 27, 2007; amended P-_____.)

28-35-181o. Specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or reference source or for certain medical uses. (a) Each application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as specified in K.A.R. 28-35-181d for use as a calibration, transmission, or reference source or for one or more of the uses listed in ~~group VI~~ 10 CFR 35.400, 35.500, 35.600, and 35.1000, as adopted by reference in K.A.R. 28-35-264, shall include the following information regarding each type of source or device:

(1) The radioactive material contained, its chemical and physical form, and amount;

(2) details of design and construction of the source or device;

(3) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and in accidents;

(4) for devices containing radioactive material, the radiation profile for a prototype device;

(5) details of quality control procedures to ensure that the production sources and devices meet the standards of the design and prototype tests;

(6) procedures and standards for calibrating sources and devices;

(7) legend and methods for labeling sources and devices as to their radioactive content;

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
APR 23 2010
APPROVED

(8) radiation safety instructions for handling and storing the source or device. These instructions shall be included on a durable label attached to the source or device. However, instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label; and

(9) the label that is to be affixed to the source or device or to the permanent storage container for the source or device. The label shall contain information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the department for distribution to persons licensed under K.A.R. 28-35-181d or under an equivalent license of the ~~U.S.~~ nuclear regulatory commission or an agreement state. Labeling for sources that do not require long-term storage may be on a leaflet or brochure that is to accompany the source.

(b)(1) If the applicant wants to have the source or device required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device, or similar sources or devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval between tests for leakage of radioactive material, information that includes the following shall be considered by the secretary:

(A) The nature of the primary containment;

(B) the method for protection of the primary containment;

(C) the method of sealing the containment;

(D) containment construction materials;

(E) the form of the contained radioactive material;

(F) the maximum temperature withstood during prototype tests;

(G) the maximum pressure withstood during prototype tests;

(H) the maximum quantity of contained radioactive material;

(I) the radiotoxicity of contained radioactive material; and

(J) the applicant's operating experience with identical sources or devices or with similarly designed and constructed sources or devices. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended July 27, 2007; amended P-_____.)

28-35-192b. Exemptions; exempt concentrations of radioactive materials. (a) Except as provided in K.A.R. 28-35-184a(e), ~~any~~ a person shall be exempt from these regulations to the extent that the person acquires, possesses, uses, ~~or transfer~~ transfers, or owns products or materials containing radioactive material in concentrations not exceeding those specified in K.A.R. 28-35-198a.

(b) ~~Any~~ A person shall be exempt from these regulations to the extent that the person acquires, possesses, uses, or transfers products containing naturally occurring radionuclides of elements with an atomic number less than 82, in isotopic concentrations not in excess of those ~~which~~ that occur naturally.

(c) This regulation shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(d) A person who manufactures, processes, or produces a product or material shall be exempt from the requirements for a license as set forth in these regulations to the extent that the transfer of the radioactive material contained in the product or material is in concentrations not in excess of the amounts specified in K.A.R. 28-35-198a and is introduced into the product or material by a licensee holding a specific license issued by the department expressly authorizing such introduction. This exemption shall not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 19 2010
APPROVED

(e) No person shall introduce radioactive material into a product or material knowing, or having reason to believe, that ~~it~~ the product or material will be transferred to a person exempt from these regulations under subsection (a) or under an equivalent regulation of the ~~U.S.~~ nuclear regulatory commission or an agreement state, except in accordance with a specific license issued under K.A.R. 28-35-181e or the general license issued in K.A.R. 28-35-194a. (Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 18 2010
APPROVED

28-35-192c. Exceptions; other radioactive material. Except for persons who apply tritium, promethium-147, or radium to, or persons who incorporate tritium, promethium-147, or radium into, the products listed in this regulation, any person shall be exempt from these regulations to the extent that the person acquires, possesses, uses, or transfers ~~the~~ any of the following products ~~listed in this subsection~~:

(a) Timepieces or hands or dials containing radium, or timepieces, hands, or dials containing not more than the following specified quantities of other radioactive materials:

(1) 25 millicuries of tritium per ~~time piece~~ timepiece;

(2) 5 millicuries of tritium per hand;

(3) 15 millicuries of tritium per dial. Bezels, when used, shall be considered as part of the dial;

(4) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;

(5) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per hand on other timepieces; ~~and~~

(6) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per dial on other ~~time pieces~~ timepieces. Bezels, when used, shall be considered as part of the dial. The levels of radiation from hands and dials containing promethium-147 shall not exceed the following, when measured through 50 milligrams per square centimeter of absorber:

(A) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 26 2010

APPROVED

(B) for pocket watches, 0.1 millirad per hour at one centimeter from any surface; and

(C) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface; and

(7) for intact timepieces manufactured before November 30, 2007, 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece;

(b) ~~lock illuminators containing not more than 15 millicures of tritium or not more than two millicuries of promethium-147 installed in automobile locks. The level of radiation from each lock illuminator containing promethium-147 shall not exceed one millirad per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;~~

~~(c)~~ balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;

~~(d) automobile shift quadrants containing not more than 25 millicuries of tritium.~~

~~(e)~~ (c) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

~~(f) thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;~~

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

MAY 18 2010

APPROVED

(d) ionization chamber smoke detectors containing not more than one microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires;

~~(g)~~ (e) electron tubes~~, if each~~. The levels of radiation from each electron tube containing radioactive material shall not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this subsection, "electron tubes" shall include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents. An electron tube ~~does~~ shall not contain more than one of the following specified quantities of radioactive material:

(1) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(2) 1 microcurie cobalt-60;

(3) 5 ~~microcurie~~ microcuries nickel-63;

(4) 30 ~~microcurie~~ microcuries krypton-85;

(5) 5 ~~microcurie~~ microcuries cesium-137; or

(6) 30 microcuries promethium-147~~. The levels of radiation from each electron tube containing radioactive material shall not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this paragraph, "electron tubes" include spark gap~~

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 19 2010
APPROVED

~~tubes, power tubes, gas tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.~~ ; and

~~(h)~~(f) ionizing radiation-measuring instruments containing, for purposes of internal calibration or standardization, sources of radioactive material. No source shall exceed the applicable quantity set forth in K.A.R. 28-35-197a. No single instrument shall contain more than 10 sources. For the purposes of this ~~paragraph~~ subsection, 0.05 ~~uCi~~ µCi of Am-241 shall be considered an exempt quantity~~; and~~ .

~~(i) spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallon (11.4 liters) per hour.~~ (Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

MAY 18 2010

APPROVED

28-35-192d. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; revoked P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

JAN 11 2010

APPROVED

28-35-192e. Exemptions; gas and aerosol detectors containing radioactive material.

(a) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material or who ~~import these products~~ initially transfer these products for sale or distribution, ~~any~~ each person ~~shall be exempt from these regulations to the extent the person~~ who acquires, receives, owns, possesses, uses, or transfers radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards shall be exempt from these regulations. Each detector shall have been manufactured, processed, produced, imported, or initially transferred in accordance with a specific license issued by the secretary pursuant to K.A.R. 28-35-181q or a license issued by the ~~United States~~ nuclear regulatory commission~~,~~ or by an agreement state pursuant to an equivalent regulation of the ~~U.S.~~ nuclear regulatory commission or ~~an~~ the agreement state.

(b) Gas and aerosol detectors previously manufactured and distributed before November 30, 2007 to general licensees in accordance with a specific license issued by an agreement state shall be exempt under subsection (a) if the device is labeled in accordance with the specific license authorizing distribution of the general licensed device~~,~~ and if the detectors meet the requirements of K.A.R. ~~28-35-181(r)~~ 28-35-181r.

(c) Each person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer these products for use pursuant to this regulation, shall apply for a license pursuant to K.A.R. 28-35-181q.

(Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

DEPT. OF ADMINISTRATION

APR 26 2010

APPROVED

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

28-35-192g. Exemptions; exempt quantities. (a) Except as provided in subsections (c) ~~and (d)~~ through (e), ~~any~~ each person ~~shall be exempt from these regulations to the extent the person~~ who acquires, possesses, uses, or transfers radioactive material in individual quantities ~~which~~ that do not exceed the applicable quantity specified in K.A.R. 28-35-197a shall be exempt from these regulations.

(b) ~~Any~~ Each person who possesses radioactive material received or acquired ~~prior to~~ before January 1, 1972 under the general license then provided in K.A.R. ~~28-35-178(A)~~ 28-35-178a shall be exempt from these regulations to the extent that the person possesses, uses, or transfers that radioactive material. This exemption ~~does~~ shall not apply to radium-226.

(c) This regulation shall not authorize the production, packaging, ~~or~~ repackaging, or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(d) No person shall, for purposes of commercial distribution, transfer radioactive material in the individual quantities specified in K.A.R. 28-35-197a knowing, or having reason to believe, that those quantities of radioactive material will be transferred to a person exempt ~~from these regulations~~ under this regulation or an equivalent regulation of the ~~U.S.~~ nuclear regulatory commission~~,~~ or an agreement state, except in accordance with a specific license issued by the secretary under K.A.R. 28-35-181r, an equivalent regulation of the ~~United States~~ nuclear regulatory commission, or an equivalent regulation of an agreement state.

(e) No person shall, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the individual quantities specified in K.A.R. 28-35-197a.

(Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

APR 26 2010

APPROVED

28-35-194a. Reciprocal recognition of licenses. (a)~~(1)~~ Subject to other provisions in this regulation, any person ~~who possesses a specific license issued by the United States nuclear regulatory commission or an agreement state, other than this state, is issued~~ may apply for a general license to conduct ~~the~~ activities ~~authorized in the specific license~~ within this state without obtaining a specific license from the secretary, if all of the following conditions are met:

(1) The person possesses a specific license issued by the nuclear regulatory commission or an agreement state, other than this state, that authorizes the proposed activities.

(2) The person does not conduct any activities authorized by any general license issued under this regulation for a period totalling more than 180 days in a calendar year.

~~(A)~~ (3) The specific license does not limit the activity authorized to a specified installation or location~~; and~~ .

~~(B)~~ (4) The person notifies the department in writing at least five days ~~prior to~~ before engaging in the activity. The notification shall indicate the location, period, and type of proposed possession and use within the state~~,~~ and shall be accompanied by a copy of the specific license. If, for a specific case, the five-day period would impose an undue hardship, the person may, upon application to the department, obtain permission by letter ~~or telegram~~, facsimile, or electronic communication to proceed~~;~~ .

~~(C)~~ (5) The person complies with all applicable regulations of the secretary and with all the terms and conditions of the specific license, except any term or condition of the license ~~which~~ that is inconsistent with these regulations~~;~~ .

ATTORNEY GENERAL
DEPT. OF ADMINISTRATION
MAY 28 2010
APPROVED BY
APR 26 2010
APPROVED

~~(D)~~ (6) The person supplies any information requested by the department~~; and~~ .

~~(E)~~ (7) The person does not transfer or dispose of radioactive material possessed or used under the general license provided in this regulation except by transfer to a person~~;~~ who meets either of the following conditions:

~~(i)~~ (A) Is specifically licensed by the department or the ~~United States~~ nuclear regulatory commission to receive the material; or

~~(ii)~~ (B) ~~who~~ is exempt from the requirements for a license for that material under K.A.R. 28-35-192a, 28-35-192b, 28-35-192c, 28-35-192d, 28-35-192e, 28-35-192f, or 28-35-192g.

(b) Any person who holds a specific license issued by the ~~U.S.~~ nuclear regulatory commission, or an agreement state ~~which~~ that authorizes the person to manufacture, transfer, install, or service a device described in K.A.R. 28-35-178b within areas subject to the jurisdiction of the licensing body is issued a general license to manufacture, install, transfer, or service those devices in this state subject to the following ~~conditions.~~ requirements:

(1) The person shall satisfy the requirements of K.A.R. 28-35-184a(e)(1) and (2).

(2) The device shall be manufactured, labeled, installed, and serviced in accordance with the provisions of the specific license issued to the person by the ~~United States~~ nuclear regulatory commission or the agreement state.

(3) The person shall ~~assure~~ ensure that any labels required to be affixed to the device, under regulations of the authority ~~which~~ that licensed the manufacture of the

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
MAY 19 2010
APPROVED

device, and ~~which~~ that bear the statement "Removal of this label is prohibited"~~,~~ are affixed to the device.

(4) The person shall furnish to each general licensee to whom the person transfers the device, or on whose premises the person installs the device, a copy of the general license issued in K.A.R. 28-35-178b.

(c) ~~The secretary may withdraw, limit, or qualify~~ Acceptance of any specific license recognized under this regulation~~,~~ or any product distributed pursuant to such a license may be withdrawn, limited, or qualified by the secretary, upon determining that the action is necessary in order to protect health or minimize danger to life or property. (Authorized by and implementing K.S.A. ~~1984 Supp.~~ 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-_____.)

28-35-212a. Occupational dose limits for adults. (a) Each licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures to the following dose limits:

(1) The annual limit shall be the more limiting of either of the following:

(A) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(B) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.50 Sv (50 rem).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities shall be the following:

(A) An eye dose equivalent of 0.15 Sv (15 rem); and

(B) a shallow dose equivalent of 0.50 Sv (50 rem) to the skin or to any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual could receive during the current year and during the individual's lifetime.

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the secretary. The assigned deep dose equivalent ~~and shallow dose equivalent~~ shall be for the portion of the body receiving the highest

exposure~~, as follows:~~. The assigned shallow dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

(1) The deep dose equivalent, eye dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

(2) If a protective apron is worn by medical fluoroscopists performing special and interventional fluoroscopic procedures and monitoring is conducted as specified in K.A.R. 28-35-217a, the use of weighting factors in determining the effective dose equivalent for external radiation may be approved by the secretary upon receipt of a written request. In no case shall the use of weighting factors be approved unless the request is accompanied by a list of the procedures to be used to ensure that exposures are maintained ALARA and the effective dose equivalent is determined as follows:

(A) If only one individual monitoring device is used and the device is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

(B) If only one individual monitoring device is used, the device is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in this regulation, then the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation.

(C) If individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(3) All individuals who are associated with the operation of an X-ray system shall be subject to the occupational exposure limits and the requirements for the determination of the doses that are specified in this regulation. In addition, each individual shall meet the following requirements:

(A) When protective clothing or devices are worn on portions of the body and one or more monitoring devices are required, at least one monitoring device shall be utilized as follows:

(i) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron;

(ii) the dose to the device, if one is used, shall be recorded as the whole-body dose based on the maximum dose attributed to any one critical organ, including the gonads, the blood-forming organs, the head and trunk, and the lens of the eye. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body;

(4) Exposure of a personnel-monitoring device to deceptively indicate a dose delivered to an individual shall be prohibited.

(5) If the individual is exposed during procedures not specifically approved, weighting factors shall not be applied.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values, in appendix B, table I, published in " appendices to part 4: standards for protection against radiation," which is adopted in K.A.R. 28-35-135a, shall be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(e) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity, in accordance with footnote 3 of appendix B published in "appendices to part 4: standards for protection against ~~radiation"~~ radiation," which is adopted in K.A.R. 28-35-135a.

(f) Each licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. (Authorized by and implementing K.S.A. 48-1607; effective, T-85-43, Dec. 19, 1984; effective May 1, 1985; amended Sept. 20, 1993; amended Oct. 17, 1994; amended Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
APR 26 2010
APPROVED

28-35-216a. Testing for leakage or contamination of sealed sources. (a) Each licensee in possession of any sealed source shall ensure that all of the following requirements are met:

(1) Each sealed source, except as specified in subsection (b), shall be tested for leakage or contamination, and the test results shall be received before the sealed source is put into use, unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

(2) Each sealed source that is not designed to emit alpha particles shall be tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the secretary, an agreement state, a licensing state, or the nuclear regulatory commission.

(3) Each sealed source designed to emit alpha particles shall be tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the secretary, an agreement state, a licensing state, or the nuclear regulatory commission.

(4) For each sealed source required to be tested for leakage or contamination, whenever there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall ensure that the sealed source is tested for leakage or contamination before further use.

(5) Tests for leakage for all sealed sources shall be capable of detecting the presence at 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the

sealed source is stored or mounted and on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples shall be obtained when the source is in the "off" position.

(b) The following sealed sources shall be exempt from testing for leakage and contamination:

(1) Sealed sources containing only radioactive material with a half-life of fewer than 30 days;

(2) sealed sources containing only radioactive material as a gas;

(3) sealed sources containing 3.7 Mbq (100 μCi) or less of beta-emitting or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

(4) sealed sources containing only hydrogen-3;

(5) seeds of iridium-192 encased in nylon ribbon; and

(6) sealed sources, except sources used in radiation therapy, that are stored, are not being used, and are identified as being in storage. The sources exempted from this test shall be tested for leakage before any use or transfer to another person, unless the source has been leak-tested within six months before the date of the use or transfer. The sources in storage shall be physically inventoried every six months and listed in the radioactive materials inventory. Each source in storage shall be tested for leakage at least every 10 years.

(c) Each test for leakage or contamination from sealed sources shall be performed by a person specifically authorized by the secretary, an agreement state, a licensing state, or the nuclear regulatory commission to perform these services.

(d) All test results shall be recorded in units of becquerel or microcurie and maintained for inspection by the department.

(e) If any test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause the source to be decontaminated and repaired or to be disposed of in accordance with these regulations. The licensee shall file a report within five days of the test with the radiation control program, ~~bureau of air and radiation,~~ Kansas department of health and environment, describing the equipment involved, the test results, and the corrective action taken. (Authorized by and implementing K.S.A. 48-1607; effective, T-85-43, Dec. 19, 1984; effective May 1, 1985; amended Dec. 30, 2005; amended July 27, 2007; amended P-_____.)

28-35-225b. Disposal of certain radioactive material. The provisions of 10 CFR 20.2008, as in effect on October 1, 2007, are hereby adopted by reference. (Authorized by and implementing K.S.A. 48-1607; effective P-_____.)

DEPT. OF ADMINISTRATION

APR 26 2010

APPROVED

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

28-35-231c. Transfer for disposal; manifests. The provisions of 10 CFR 20.2006 as in effect on ~~September 21, 1998~~ October 1, 2007, including appendix G to 10 CFR part 20 as in effect on ~~October 10, 2003~~ November 16, 2005, are hereby adopted by reference. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

JAN 13 2010

APPROVED

28-35-242. General requirements. (a) Waiver of requirements. Compliance with the specific requirements of these regulations relative to an existing machine or installation may be waived by the secretary if the registrant provides an alternative to the requirement that provides radiation protection equal to that prescribed in part 4 of these regulations.

(b) Responsibility to meet requirements. A person shall not make, sell, lease, transfer, lend, or install X-ray or fluoroscopic equipment, or the supplies used in connection with this equipment, unless both of the following conditions are met:

(1) Those supplies and equipment, when properly placed in operation and properly used, will meet the requirements of parts 1, 4, and 5~~,~~ and the applicable regulations under parts 7, 8, and 10 of these regulations.

(2) The person delivers, if applicable, cones or collimators, filters, appropriate timers, and fluoroscopic shutters.

(c) Limitations on human use. An individual shall not be exposed to the useful beam, unless the exposure is for healing arts purposes and each exposure has been authorized by one of the following:

(1) A licensed practitioner of the healing arts~~,~~ ;

(2) a physician assistant licensed by the state board of healing arts, when working under the supervision and direction of a person licensed to practice medicine or surgery;

(3) an advanced registered nurse practitioner who holds a certificate of qualification from the state board of nursing, when working under the supervision and direction of a person licensed to practice medicine or surgery; or

(4) ~~by~~ an individual licensed to practice dentistry or podiatry within the authority granted to the individual by Kansas licensing laws applying to dentists and podiatrists.

(d) Prohibited uses. Deliberate exposure for the following purposes shall be specifically prohibited ~~under this subsection~~:

(1) Exposure of an individual for patient positioning, training, demonstration, or other purposes, unless a healing arts purpose exists and a proper prescription has been provided; and

(2) exposure of an individual for the purpose of healing arts screening without the prior written approval of the department, except mammography screening, if the facility is certified to perform mammography by the food and drug administration. Each person requesting approval for healing arts screening shall submit the information outlined in K.A.R. 28-35-255. Each person requesting approval for a healing arts screening shall ~~immediately~~ notify the department within 30 days if any of the information submitted becomes invalid or outdated. (Authorized by and implementing K.S.A. 48-1607; effective Jan. 1, 1970; amended Jan. 1, 1972; amended May 1, 1976; amended Sept. 20, 1993; amended Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

MAY 18 2010

APPROVED

28-35-264. General requirements. The provisions of 10 CFR part 35, as in effect on ~~May 2, 2005~~ January 15, 2010, are hereby adopted by reference, with the changes specified in this regulation.

(a) For the purposes of part 6, "byproduct material" shall mean all radioactive material regulated by the department.

(b) All reports required by this regulation shall be submitted to the department.

(c) The following sections shall be deleted:

(1) 10 CFR 35.1, "purpose and scope";

(2) 10 CFR 35.2, "definitions," except that the definitions of the following terms shall be retained:

(A) "Authorized medical physicist";

(B) "authorized nuclear pharmacist";

(C) "authorized user";

(D) "medical event";

(E) "prescribed dose"; and

~~(E)~~ (F) "radiation safety officer";

(3) 10 CFR 35.8, "information collection requirements: OMB approval";

(4) 10 CFR 35.18, "license issuance";

(5) 10 CFR 35.19, "specific exemptions";

(6) 10 CFR 35.26 (a)(1), "radiation protection program changes";

(7) 10 CFR 35.4001, "violations"; and

(8) 10 CFR 35.4002, "criminal penalties."

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
JAN 15 2010
APPROVED

(d) Wherever the following CFR references occur within 10 CFR part 35, these references shall be replaced with the specified references to regulations and parts in this article:

(1) "10 CFR 19.12" shall be replaced with "K.A.R. 28-35-333, 'instructions to workers.' "

(2) "10 CFR part 20" shall be replaced with "part 4, 'standards for protection against radiation.' "

(3) "10 CFR 20.1101" shall be replaced with "K.A.R. 28-35-211d, 'radiation protection programs.' "

(4) "10 CFR 20.1301(a)(1) and 20.1301(c)" shall be replaced with "K.A.R. 28-35-214a."

(5) "10 CFR 20.1501" shall be replaced with "K.A.R. 28-35-217b."

(6) "10 CFR part 30" shall be replaced with "part 3, 'licensing of sources of radiation.' "

(7) "10 CFR 32.72" shall be replaced with " K.A.R. 28-35-181m, 'specific licenses to manufacture and distribute radiopharmaceuticals containing radioactive material for medical use under group licenses,' and K.A.R. 28-35-181n, 'specific licenses to manufacture and distribute generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material.' "

ATTORNEY GENERAL

MAY 28 2010

APPROVED BY

DEPT. OF ADMINISTRATION

JAN 13 2010

APPROVED

(8) "10 CFR 32.74" shall be replaced with "K.A.R. 28-35-181o, 'specific licenses to manufacture and distribute sources and devices for use as a calibration or reference source, or for certain medical uses.' "

(9) "10 CFR 33.13" shall be replaced with "K.A.R. 28-35-182b, 'qualifications for a type A specific license of broad scope.' "

(e) Wherever the following terms occur within 10 CFR part 35, these terms shall be replaced with "department":

(1) "Commission";

(2) "NRC operation center"; and

(3) "NRC regional office."

(f) The following changes shall be made to the sections specified:

(1) 10 CFR 35.6(b)(1) and (c)(1) shall be replaced with the following text:

"Obtain review and ~~approved~~ approval of the research as specified in 45 CFR 46.111, 'criteria for IRB approval of research'; and".

(2) 10 CFR 35.6(b)(2) and (c)(2) shall be replaced with the following text:

"Obtain informed consent from the human research subject as specified in 45 CFR 46.116, 'general requirements for informed consent.' "

(3) 10 CFR 35.10, subsection (a) shall be deleted.

(4) In 10 CFR 35.10(d), the date "October 24, 2002" shall be replaced with "the effective date of these regulations," and in 10 CFR 35.10(b) and (c), the date "October 25, 2005" shall be replaced with "two years from the effective date of these regulations."

ATTORNEY GENERAL
MAY 28 2010
APPROVED BY

DEPT. OF ADMINISTRATION
JAN 13 2010
APPROVED

(5) 10 CFR 35.12(b)(1) and (c)(1)(i) shall be replaced with the following text: "submitting a form specified by the department that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized users, authorized physicists, and authorized pharmacists."

(6) In 10 CFR 35.57(a)(1) and (b)(1), the date "October 24, 2002" shall be replaced with "the effective date of these regulations."

(7) In 10 CFR 35.57(a)(2) and (b)(2), the date "April 29, 2005" shall be replaced with "the effective date of these regulations."

(8) In 10 CFR 35.432(a), the date "October 24, 2002" shall be replaced with "the effective date of these regulations."

(9) In 10 CFR 35.3045, the footnote shall be deleted, and in subsection (a) the words "or any radiation-producing device" shall be added before the words "results in."

(10) 10 CFR 35.3047(d) shall be replaced with the following text: "The licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo or fetus, or nursing child that requires a report in paragraphs (a) or (b) in this section."

(11) In 10 CFR 35.3067, the phrase "with the department" shall be inserted after the word "report" in the first sentence, and the second sentence shall be deleted.

(Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-_____.)

ATTORNEY GENERAL DEPT. OF ADMINISTRATION

MAY 28 2010 JAN 13 2010

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28-35-334. ~~Notifications and~~ Reports to individuals. ~~(a)~~ Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this ~~section~~ regulation.

(a) The information reported shall include data and results obtained pursuant to the requirements of these regulations~~;~~ or any order of the secretary or license condition, as shown in records maintained by the licensee or registrant pursuant to K.A.R. 28-35-227h ~~of these regulations~~. Each ~~notification and~~ report shall meet the following requirements:

(1) Be in writing;

(2) include appropriate identifying data ~~such as~~, including the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(3) include the individual's exposure information; and

(4) contain the following statement:

"This report is furnished to you under the provisions of Kansas Administrative ~~Rule and~~ Regulation 28-35-334. You should preserve this report for further reference."

(b) Each licensee or registrant shall ~~furnish each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to K.A.R. 28-35-227h(b)~~ make dose information available to individual workers shown in records maintained by the licensee or registrant pursuant to K.A.R. 28-35-227h. Each licensee or registrant shall provide an annual report to each individual worker monitored

ATTORNEY GENERAL
MAY 28 2010
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DEPT. OF ADMINISTRATION
MAY 19 2010
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pursuant to K.A.R. 28-35-217b of the dose received in that monitoring year if either of the following situations occurs:

(1) The individual's dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue.

(2) The individual requests an annual dose report.

(c) Each licensee or registrant shall furnish ~~to the worker~~ a written report of ~~the~~ a worker's exposure to sources of radiation or radioactive material at the request of ~~a~~ the worker if the worker was formerly engaged in activities controlled by the licensee or registrant. The report shall be furnished within 30 days from the date of the request~~,~~ or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover, within the period of time specified in the request, the dose record for each year the worker was required to be monitored pursuant to K.A.R. 28-35-217b ~~of these regulations~~. The report shall also include the period of time in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to K.A.R. 28-35-229a(a)(1)~~,~~ and (b)(1) ~~of these regulations~~ to report to the department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide to the individual a

written report of the individual's exposure data included in the report. ~~These reports~~ This report shall be transmitted to the individual at a time not later than the transmittal of the report to the department.

(e) At the request of a worker who is terminating employment with the licensee or registrant that involves exposure to radiation or radioactive material, or at the request of a worker who, while employed by another person, is terminating an assignment to work involving radiation dose in the licensee's facility, each licensee or registrant shall provide to the worker, or the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year. The report shall be provided at the worker's termination. The licensee or registrant may provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such. (Authorized by K.S.A. ~~1993 Supp.~~ 48-1607; implementing K.S.A. ~~1993 Supp.~~ 48-1604, 48-1607, and 48-1609; effective May 1, 1976; amended, T-85-43, Dec. 19, 1984; amended May 1, 1985; amended Oct.17, 1994; amended P-_____.)

DEPT. OF ADMINISTRATION

APR 27 2010

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MAY 28 2010

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28-35-346. Leak testing of sealed sources. (a) Requirements. Each licensee using any sealed source of radioactive material shall have the source tested for leakage as specified in subsection (c). A record of leak test results shall be kept in units of microcuries and maintained for inspection by the department. The licensee shall keep the records of the results for three years after the leak test is performed.

(b) Method of testing. Each test for leakage shall be performed only by a person specifically authorized to perform such a test by the department, the ~~U.S.~~ nuclear regulatory commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, the source holder, or the surface of the device in which the source is stored or mounted and on which one could expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and shall be performed by a person specifically authorized to perform such a test by the department, the ~~U.S.~~ nuclear regulatory commission, an agreement state, or a licensing state.

(c) Interval of testing. Each sealed source of radioactive material, except an energy compensation source (ECS), shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within the six months before the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source ~~may~~ could be leaking, ~~it~~ the sealed source shall be removed from service immediately and tested for leakage as soon as practical. Each ECS that is not exempt from testing in accordance with subsection (e)

~~of this regulation~~ shall be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS shall not be used until tested.

(d) Leaking or contaminated sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these regulations. Each licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, shall have the equipment decontaminated or disposed of by ~~an NRC~~ a nuclear regulatory commission licensee or an agreement state licensee that is authorized to perform these functions. A report describing the equipment involved, the test result, and the corrective action taken shall be filed with the department within five days after receiving the test results.

(e) Exemptions. The following sources shall be exempt from the periodic leak test requirements of this regulation:

(1) Hydrogen-3 (tritium) sources;

(2) sources of radioactive material with a half-life of 30 days or less;

(3) sealed sources of radioactive material in gaseous form;

(4) sources of radioactive material emitting beta, beta-gamma, or gamma radiation, with an activity of not more than 100 microcuries (3.7 Mbq); and

(5) sources of alpha-emitting radioactive material with an activity of not more than 10 microcuries (0.370 MBq). (Authorized by and implementing K.S.A 48-1607; effective Sept. 20, 1993; amended Dec. 30, 2005; amended P-_____.)

28-35-411. Table of quantities of radioactive material; need for contingency plan.

Quantities of Radioactive Materials Requiring Consideration of the Need for a Contingency Plan for Responding to a Release

Radioactive Material[1]	Release Fraction	Quantity (GBq)	Quantity (Ci)
Actinium-228	0.001	148,000	4,000
Americium-241	0.001	74	2
Americium-242	0.001	74	2
Americium-243	0.001	74	2
Antimony-124	0.01	148,000	4,000
Antimony-126	0.01	222,000	6,000
Barium-133	0.01	370,000	10,000
Barium-140	0.01	1,110,000	30,000
Bismuth-207	0.01	185,000	5,000
Bismuth-210	0.01	22,200	600
Cadmium-109	0.01	37,000	1,000
Cadmium-113	0.01	2,960	80
Calcium-45	0.01	740,000	20,000
Californium-252	0.001	333	9 (20 mg)
Carbon-14 (Non-CO)	0.01	1,850,000	50,000
Cerium-141	0.01	370,000	10,000
Cerium-144	0.01	11,100	300

Cesium-134	0.01	74,000	2,000
Cesium-137	0.01	111,000	3,000
Chlorine-36	0.5	3,700	100
Chromium-51	0.01	11,100,000	300,000
Cobalt-60	0.001	185,000	5,000
Copper-64	0.01	7,400,000	200,000
Curium-242	0.001	2,220	60
Curium-243	0.001	110	3
Curium-244	0.001	148	4
Curium-245	0.001	74	2
Europium-152	0.01	18,500	500
Europium-154	0.01	14,800	400
Europium-155	0.01	111,000	3,000
Gadolinium-153	0.01	185,000	5,000
Gold-198	0.01	1,110,000	30,000
Hafnium-172	0.01	14,800	400
Hafnium-181	0.01	259,000	7,000
Holmium-166m	0.01	3,700	100
Hydrogen-3	0.5	740,000	20,000
Indium-114m	0.01	37,000	1,000
Iodine-124	0.5	370	10

Iodine-125	0.5	370	10
Iodine-131	0.5	370	10
Indium-114m	0.01	37,000	1,000
Iridium-192	0.001	1,480,000	40,000
Iron-55	0.01	1,480,000	40,000
Iron-59	0.01	259,000	7,000
Krypton-85	1.0	222,000,000	6,000,000
Lead-210	0.01	296	8
Manganese-56	0.01	2,220,000	60,000
Mercury-203	0.01	370,000	10,000
Molybdenum-99	0.01	1,110,000	30,000
Neptunium-237	0.001	74	2
Nickel-63	0.01	740,000	20,000
Niobium-94	0.01	11,100	300
Phosphorus-32	0.5	3,700	100
Phosphorus-33	0.5	37,000	1,000
Polonium-210	0.01	370	10
Potassium-42	0.01	333,000	9,000
Promethium-145	0.01	148,000	4,000
Promethium-147	0.01	148,000	4,000
Radium-226	0.001	3,700	100

ATTORNEY GENERAL

MAY 28 2010

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APR 27 2010

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Ruthenium-106	0.01	7,400	200
Samarium-151	0.01	148,000	4,000
Scandium-46	0.01	111,000	3,000
Selenium-75	0.01	370,000	10,000
Silver-110m	0.01	37,000	1,000
Sodium-22	0.01	333,000	9,000
Sodium-24	0.01	370,000	10,000
Strontium-89	0.01	111,000	3,000
Strontium-90	0.01	3,330	90
Sulfur-35	0.5	3,330	900
Technetium-99	0.01	370,000	10,000
Technetium-99m	0.01	14,800,000	400,000
Tellurium-127m	0.01	185,000	5,000
Tellurium-129m	0.01	185,000	5,000
Terbium-160	0.01	148,000	4,000
Thulium-170	0.01	148,000	4,000
Tin-113	0.01	370,000	10,000
Tin-123	0.01	111,000	3,000
Tin-126	0.01	37,000	1,000
Titanium-44	0.01	3,700	100
Vanadium-48	0.01	259,000	7,000

Xenon-133	1.0	33,300,000	900,000
Yttrium-91	0.01	74,000	2,000
Zinc-65	0.01	185,000	5,000
Zirconium-93	0.01	14,800	400
Zirconium-95	0.01	185,000	5,000
Any other beta-gamma emitter	0.01	370,000	10,000
Mixed fission products	0.01	37,000	1,000
Contaminated equipment:			
beta-gamma emitters	0.001	370,000	10,000
Irradiated material, in any form other than solid noncombustible	0.01	370,000	10,000
Irradiated material that is solid and noncombustible	0.001	370,000	10,000
Mixed radioactive waste:			
beta-gamma emitters	0.01	37,000	1,000
Packaged mixed waste[2]:			
beta-gamma emitters	0.001	370,000	10,000
Any other alpha emitter	0.001	74	2

Contaminated equipment:			
alpha emitters	0.0001	740	20
Packaged waste[2]:			
alpha emitters	0.0001	740	20

[1] For combinations of radioactive materials, the licensee shall be required to consider whether a contingency plan is needed if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed in this table for that material exceeds one.

[2] Waste packaged in type B containers shall not require a contingency plan.

(Authorized by K.S.A. 48-1607; implementing K.S.A. 48-1602; effective Dec. 30, 2005; amended P-_____.)